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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/852,966	05/10/2001	Rima Kaddurah-Daouk	AVZ-020CN	5588

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LAHIVE & COCKFIELD
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EXAMINER
KIM, VICKIE Y

ART UNIT	PAPER NUMBER
1614	10

DATE MAILED: 06/04/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	pplicant(s)	
	09/852,966	KADDURAH-DAOUK, RIMA	
	Examin r	Art Unit	
	Vickie Kim	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 68-88 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 68-88 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 9 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Status of Application

Acknowledgement is made of amendment filed March 06, 2003. As requested, claims 1-67 are canceled and new claims 68-88 are added.

The claims 68-88 are pending, and presented for the examination.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 68-41, 74, 84-87 are rejected under 35 U.S.C. 102(b) as being by Lee et al (US 5,605,687).

The claims are drawn to a method of increasing energy reserves, sustaining energy production or modulating energy flow in the skin using creatine or creatine derivatives wherein said method is utilized for treating undesirable skin conditions such as wrinkles, skin disorder associated with aging or stress.

US'687 teaches a treatment of tissue damage due to ionizing irradiation injuries, surgical injury and "burns" of a chemical or thermal nature via promoting cellular energy store regeneration, see column 5, lines 26-27 and column 13, lines 23. US'687 also teaches that phosphocreatine(creatine phosphate) is using effectively to recharge the energy store into the cellular membrane of injured tissue and potentiate the tissue repairing and healing processes. It further teaches that topical application of

phosphocreatine into the skin to treat surface lesions, see column 8, lines 58-68 and column14, lines 2-8. For instance, the topical application of phosphocreatine (see column 8, lines 58-88) is carried out by applying topical phosphyocreatine (10%w/v) composition into the damaged area, wrapped with sterile dressings, and reapplied as necessary.

Thus, all the critical elements required by the instant claims are well taught by the cited reference. It is noted that the limitation recited in the claims 68-70 (i.e. increasing energy reserves, sustaining energy production or modulating energy flow in the skin) is considered to be underlying mechanism and inherently possessed by creatine compounds administration where said underlying mechanism(biological pathway) is naturally occurring when the creatine(or creatine derivative) containing composition is topically administered into the injured skin tissue(see page 3, line 22-24) to recharge the cellular energy.

Although Lee's patent is mainly directed to a electrical tissue injury using poloxamer 188 in combination with phosphocreatine, it acknowledges that phosphocreatine(as a secondary active principle) itself is capable of recharging cellular energy stores and potentiating cell repair and survival and the intended use is carried out via said biological action as stated in abstract. The claimed subject matter is considered to be not novel and well known knowledge in the field at the time of the invention was made as evidenced by the cited reference. Thus, the claimed subject matter is not patentably distinguished over the prior art of the record.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 68-88 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lee et al (US 5,605,687) in view of Hoppe et al(US 6261575).

Lee's teaching is mentioned immediately above in 102 rejection(supra).

Applicant's claims differ because they require skin conditions(e.g.wrinkles, skin changes associated with aging, stress or fatigue); other creatine salt form such as monohydrate or citrate; other beneficial additives such as antioxidant(e.g.CoQ10, vitamine E), an energy enhancing agents(ATP, nicotinamide), sunscreen(zinc Oxide).

Hoppe teaches a therapeutic composition for treating skin conditions such as wrinkles and other changes associated with aging using a combination composition comprising CoQ10(ubiquinone), vitamine C and E, ATP, nicotinamide, sunscreens to obtain maximum therapeutic efficacy, see column 5-6.

The minor variations , for example, it is well known in the art that pharmacore(creatine) which is responsible for the therapeutic effectiveness and it is always desired to have more selection options for therapeutic modalities; adding art

recognized energy enhancing agents(e.g. ATP, nicotinamide, pyruvate), beneficial additives such as zinc oxide as a sunscreen or an antioxidant(e.g. ascorbic acid or tocopherol) into the said treatment to enhance the therapeutic effectiveness, in order to determine the most effective treatment is well within the skilled level of artisan having ordinary skill in the art and is obvious.

5. Claims 68-88 are rejected under 35 U.S.C. 103(a) as being unpatentable over Greff(FR 2725896: English translated abstract is also provided, see PTO-892) in view of Yu et al (US 5886041) or Hoppe et al(US 6261575).

FR'896 teaches a cosmetic composition and its use in the treatment of skin wrinkles or cellular growth wherein said cosmetic composition is prepared and used to stimulate creatine (phophocreatine) synthesis in vivo. It teaches the improvement on energy reserve, sustaining energy production and modulating energy flow in the skin for treating skin conditions such as aged skin, wrinkles, see abstract and pages 1-2.

Applicant's claims differ in that because they require creatine or its derivative to be an active component in said cosmetic composition whereas FR'896 teaches amino acids containing composition to produce creatine(phosphocreatine) in vivo because it is difficult to make stable phosphocreatine containing composition, see page 2, lines 5-7.

However, it would have been obvious to make creatine containing topical composition when Greff(FR'896) is taken in view of Yu et al(US'041) or Hoppe et al(US'575) because aforementioned technical difficulty to make stable cosmetic product is overcame as evidenced by Yu or Hoppe's teaching.

Yu et al teaches a stable cosmetic/pharmaceutical topical composition comprising creatine compounds. For instance, Yu et al teach a physically stable therapeutic composition for treating undesirable skin conditions (e.g. wrinkles, dry skin, or other skin changes associated with aging) using a stable topical composition comprising creatine or creatinine; and alpha keto acids and other hydroxy acids, see abstract, claim 1 and column 32, lines 5-11. Furthermore, Yu et al contemplate several exemplified compositions 33-34.

Hoppe et al(US' 575) also teach a stable cosmetic composition for treating skin wrinkles and comprising creatine as a secondary active principle, see column 5, lines 30-35.

As to the limitations required by the dependent claims such as creatine monohydrate or citrate (instant claims 72- 73), a skin preserving agent such as antioxidant(claims 75-77 & 80-81), an energy enhancing agent such as nicotinamide, pyruvate or ATP(claims 78-79), and zinc oxide as a species of sunscreen(claims 82-83) are conventional knowledge and considered to be well with the skilled level of the artisan as evidenced by both Yu and Hope's references(see entire text), and obvious, absent evidence to the contrary.

Thus, one would have been motivated to supply a stable topical cosmetic/pharmaceutical composition containing creatine or phosphocreatine as an active component for treating skin wrinkles and other skin conditions including free radical related, with reasonable expectation of success, because direct supply of phosphocreatine or creatine via topical application into the affected tissue cell

membrane maximizes the therapeutic efficacy avoiding extra time for in-vivo synthesis(shortening the activation time), and reduced any undesired adverse effect since creatine is naturally existing material in the body tissues.

For the reasons mentioned above, all the claimed subject is not patentably distinct over the prior art of the record.

Double Patenting

6. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7. Claims 68-88 are rejected under the judicially created doctrine of double patenting over claims of U. S. Patent No. 6242491 since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent.

The subject matter claimed in the instant application is fully disclosed in the patent and is covered by the patent since the patent and the application are claiming common subject matter, as follows: US'491 claimed a method of treating skin conditions such as wrinkles and other symptoms associated with skin aging. The instant claims are directed to a method of modulating energy status in the cell for treating skin

conditions such as wrinkles using creatine compounds. The claimed subject matter is considered to be underlying mechanism and inherently possessed by creatine administration where said underlying mechanism(biological pathway) is naturally occurring when the creatine(or creatine derivatives) containing composition is topically administered into affected area having wrinkles or skin changes associated stress, aging, fatigue, or free radical. Thus, the claimed subject matter should be encompassed by the teaching of the US patent'491.

Furthermore, there is no apparent reason why applicant was prevented from presenting claims corresponding to those of the instant application during prosecution of the application which matured into a patent. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

Conclusion

8. No claim is allowed.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vickie Kim whose telephone number is 703-305-1675. The examiner can normally be reached on Tuesday-Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on 703-308-4725. The fax phone numbers for the organization where this application or proceeding is assigned are 703-746-3165 for regular communications and 703-746-3165 for After Final communications. Any inquiry of a general nature or

relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

Vickie Kim,
Patent examiner
June 2, 2003
Art unit 1614